

### REMARKS

Claims 1-6 and 8-13 are pending. Claims 8-13 have been withdrawn. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

The Examiner has maintained the rejection of: Claims 1-7 under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Patent No. 4,486,436 (Sunshine et al.) and U.S. Patent No. 4,943,565 (US '565 Tencza et al.); and Claims 1-7 under 35 U.S.C. § 103(a) for allegedly being obvious over Canadian Patent No. 1,336,687 (CA '687 Tencza et al.). Applicants respectfully traverse these rejections, in view of the comments set forth below.

As noted in Applicants previous response, Claim 7 was cancelled in the amendment filed on July 30, 2008. As such, the rejections of Claim 7 are moot.

Claim 1 is directed to a solid pharmaceutical dosage form comprising caffeine, a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof, and a cephalagic, wherein the caffeine is in the form of uncoated particles having an average particle size of about 70 to 600 microns, and wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Applicants maintain that Sunshine et al. does not disclose a composition comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Accordingly, Claim 1 is patentable over Sunshine et al.

US '565 Tencza et al. discloses sample CW-3446-54B, which is formulated with 5 mg of Polyplasdone XL-10 (see col. 7, lines 30-33). As noted in Applicants' response dated

January 14, 2009, Polyplasdone XL-10 is a non-ionic crosslinked PVP Crospovidone. Thus, it is respectfully submitted that Sample CW-3446-54B does not include a disintegrant from the list of disintegrants recited in Claim 1 of the present application. That is, Polyplasdone XL-10 is not a sodium starch glycolate and is not a crosslinked carboxymethylcellulose. As such, Sample CW-3446-54B does not fall within the compositional limitations of Claim 1. US '565 Tencza et al. also discloses a sample CW 3446-58 that is formulated with low-substituted Hydroxypropyl Cellulose Grade LH-21 as the disintegrant. Low-substituted Hydroxypropyl Cellulose Grade LH-21 is not a sodium starch glycolate and is not a crosslinked carboxymethylcellulose. As such, Sample CW-3446-58 also does not fall within the compositional limitations of Claim 1. Therefore, Claim 1 is patentable over US '565 Tencza et al.

Accordingly, Applicants respectfully submit that US '565 Tencza et al. does not remedy the deficiencies of Sunshine et al. Neither Sunshine et al. nor US '565 Tencza et al. disclose or teach a solid pharmaceutical dosage form comprising caffeine and a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. As such, Claim 1 is patentable over Sunshine et al. and US '565 Tencza et al. whether considered separately or in combination.

CA '687 Tencza et al. discloses a sample CW-3708-29B, where Crospovidone XL-10 and Povidone are utilized as disintegrants. Here again, the disintegrants included in sample CW-3708-29B do not fall within the limitations set forth in Claim 1. That is Crospovidone XL-10 and Povidone, do not qualify as a disintegrant from the defined grouping

in Claim 1, i.e., sodium starch glycolate and/or crosslinked carboxymethylcellulose. As such, Claim 1 is patentable over CA '687 Tencza et al.

Claims 2-6 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 are patentable over Sunshine et al., US '565 Tencza et al. and CA '687 Tencza et al., taken separately or in combination.

In view of the foregoing remarks, Applicant respectfully requests favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Victor Tsu/

---

Attorney for Applicants  
Victor Tsu  
Registration No. 46,185

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003